



TRANSMITTAL OF APPEAL BRIEF

Docket No.
NY-QMET 201-US

In re Application of: John E. Ware et al.

Application No. 09/873,500-Conf. #5112	Filing Date June 4, 2001	Examiner L. G. Le	Group Art Unit 3626
---	-----------------------------	----------------------	------------------------

Invention: METHOD AND SYSTEM FOR HEALTH ASSESSMENT AND MONITORING

TO THE COMMISSIONER OF PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal
filed: May 12, 2008

The fee for filing this Appeal Brief is \$ 510.00

Large Entity Small Entity

A petition for extension of time is also enclosed.

The fee for the extension of time is _____

A check in the amount of _____ is enclosed.

Charge the amount of the fee to Deposit Account No. 50-0624
This sheet is submitted in duplicate.

Payment by credit card. Form PTO-2038 is attached.

The Director is hereby authorized to charge any additional fees that may be required or
credit any overpayment to Deposit Account No. 50-0624
This sheet is submitted in duplicate.

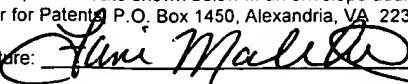

C. Andrew Im
Attorney Reg. No. : 40,657
FULBRIGHT & JAWORSKI L.L.P.
666 Fifth Avenue
New York, New York 10103
(212) 318-3359

Dated: July 14, 2008

Appeal Brief Transmittal

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EM 155747325 US, on the date shown below in an envelope addressed to:
MS Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: July 14, 2008

Signature: 

(Fani Malikouzakis)



Application No. (if known): 09/873,500

Attorney Docket No.: NY-QMET 201-US

Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. EM 155747325 US in an envelope addressed to:

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on July 14, 2008
Date



Signature

C. Andrew Im

Typed or printed name of person signing Certificate

40,657
Registration Number, if applicable

(212) 318-3359
Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Fee Transmittal (1 page)
Appeal Brief
Appeal Brief Transmittal (1 page)
Payment by credit card. Form PTO-2038 is attached (1 page)
Charge \$510.00 to credit card
Certificate of Express mailing



Under the Paperwork Reduction Act of 1995, no person are required to respond to a collection of information unless it displays a valid OMB control number.

Effective on 12/08/2004.

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL

For FY 2008

Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 510.00)

Complete if Known

Application Number	09/873,500-Conf. #5112
Filing Date	June 4, 2001
First Named Inventor	John E. Ware
Examiner Name	L. G. Le
Art Unit	3626
Attorney Docket No.	NY-QMET 201-US

METHOD OF PAYMENT (check all that apply)

Check Credit Card Money Order None Other (please identify): _____

Deposit Account Deposit Account Number: 50-0624 Deposit Account Name: Fulbright & Jaworski L.L.P.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

Charge fee(s) indicated below Charge fee(s) indicated below, except for the filing fee
 Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 Credit any overpayments

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

<u>Application Type</u>	<u>FILING FEES</u>		<u>SEARCH FEES</u>		<u>EXAMINATION FEES</u>		
	<u>Fee (\$)</u>	<u>Small Entity</u>	<u>Fee (\$)</u>	<u>Small Entity</u>	<u>Fee (\$)</u>	<u>Small Entity</u>	<u>Fees Paid (\$)</u>
Utility	310	155	510	255	210	105	
Design	210	105	100	50	130	65	
Plant	210	105	310	155	160	80	
Reissue	310	155	510	255	620	310	
Provisional	210	105	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description

Each claim over 20 (including Reissues)

Small Entity

<u>Fee (\$)</u>	<u>Fee (\$)</u>
50	25

Each independent claim over 3 (including Reissues)

210 105

Multiple dependent claims

370 185

<u>Total Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
- =	x	=	

HP = highest number of total claims paid for, if greater than 20.

<u>Multiple Dependent Claims</u>	
<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>

<u>Indep. Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
- =	x	=	

HP = highest number of independent claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$260 (\$130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

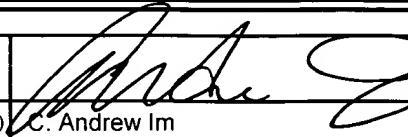
<u>Total Sheets</u>	<u>Extra Sheets</u>	<u>Number of each additional 50 or fraction thereof</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
		/50 =	(round up to a whole number) x	=
- 100 =				

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): 1402 Filing a brief in support of an appeal

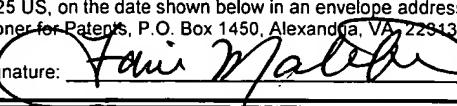
510.00

SUBMITTED BY				
Signature		Registration No. (Attorney/Agent)	40,657	Telephone (212) 318-3359
Name (Print/Type)	C. Andrew Im		Date	July 14, 2008

Fee Transmittal

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EM 155747325 US, on the date shown below in an envelope addressed to: MS Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: July 14, 2008

Signature:  (Fani Malikouzakis)

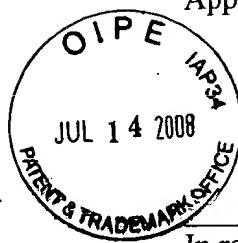
7-15-08

JK

AF

Application No.: 09/873,500

Docket No.: NY-QMET 201-US



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
John E. Ware

Application No.: 09/873,500

Confirmation No.: 5112

Filed: June 4, 2001

Art Unit: 3626

For: METHOD AND SYSTEM FOR HEALTH
ASSESSMENT AND MONITORING

Examiner: Le, Ling Giang

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under § 41.37(a), this brief is filed within two months of the Notice of Appeal filed in this case on May 12, 2008, and is in furtherance of said Notice of Appeal.

The fees required under § 41.20(b)(2) are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

07/15/2008 HLE333 00000064 09873500

01 FC:1402

510.00 DP

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1205:

I.	REAL PARTY IN INTEREST	3
II.	RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS	4
III.	STATUS OF CLAIMS	5
A.	Total Number of Claims in Application.....	5
B.	Current Status of Claims.....	5
C.	Claims On Appeal	5
IV.	STATUS OF AMENDMENTS	6
V.	SUMMARY OF CLAIMED SUBJECT MATTER	7
VI.	GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL.....	10
VII.	ARGUMENT	11
A.	The Combined References Do Not Teach Or Suggest All the Claim Limitations.....	11
1.	Rejection Under 35 U.S.C. § 103 Over Ware in View of Lewis (Claims 1-6, 8-23, 25-27, 29-41)	11
2.	Rejection Under 35 U.S.C. § 103 Over Ware in View of Bair (Claims 42-45).....	16
B.	There is No Motivation To Combine References (Claims 1-6, 8-23, 25-27, 29-41, 42-45)	17
VIII.	CONCLUSION	19
	CLAIMS APPENDIX (37 C.F.R. § 41.37(C)(VIII)).....	20
	EVIDENCE APPENDIX (37 C.F.R. § 41.37(C)(IX))	28
	RELATED PROCEEDINGS APPENDIX (37 C.F.R. § 41.37 (C)(X)).....	29

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is: **QualityMetric, Inc.**

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

Applicant filed a prior appeal in this application Serial No. 09/873,500, but Applicant opted to file an RCE instead of going forward with the appeal at the time.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 40 claims pending in application.

B. Current Status of Claims

- 1. Claims canceled: 7, 11, 16, 24, 28**
- 2. Claims withdrawn from consideration but not canceled: None**
- 3. Claims pending: 1-6, 8-10, 12-15, 17-23, 25-27, 29-45**
- 4. Claims allowed: None**
- 5. Claims rejected: 1-6, 8-10, 12-15, 17-23, 25-27, 29-45**

C. Claims On Appeal

The claims on appeal are claims 1-6, 8-10, 12-15, 17-23, 25-27, 29-45.

IV. STATUS OF AMENDMENTS

Applicant filed no response to the Final Office Action dated February 11, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A concise explanation of the subject matter defined in each of the independent claims separately argued in this appeal, which refers to the specification and to the drawings by reference characters, is provided below. All references to the specification and drawings are made by way of example for the convenience of the Board, as it is possible that other areas of the specification and drawings may contain further descriptive material. No limitations on the meaning of the following claim language is intended.

According to independent claim 1, a method of assessing the health status or health care of a patient comprises the steps of: generating a customized test, based on the patient's characteristics and one or more health domains selected by a patient or a health care provider, said test having a plurality of questions for said patient in accordance with said selected health domains (pg. 14, ln. 28 – pg. 15, ln. 20; pg. 25, lns. 3- 8; pg. 34, lns. 5-20; 504-518 of Figure 5); administering said test by providing one question at a time to said patient (e.g. pg. 25, ln. 8-17, pg. 34, lns. 15-16, 510 and 518 of Figure 5); and after each question: evaluating answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score (e.g., pg. 34, lns. 16-20; 308 of Figure 310); varying a threshold as a function of said estimated score (e.g., pg. 34, lns. 18-28, Figure 3); and dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold (e.g., pg. 34, ln. 18 - pg. 35, ln. 2; pg. 47, lns. 18-19; Figure 3).

According to independent claim 18, a computer based system for assessing the health status or health care of a patient (pages 40-41), comprises: a test module for generating a customized test, based on the patient's characteristics and one or more health domains selected by a patient or a health care provider, said test having a plurality of questions for said patient in accordance with said selected health domains (pg. 14, ln. 28 – pg. 15, ln. 20; pg. 25, lns. 3- 8; pg. 34, lns. 5-20; 504-518 of Figure 5); an administration module for administering said test by providing one question at a time to said patient (e.g. pg. 25, ln. 8-17, pg. 27, lns. 7-9; pg. 34, lns.

15-16, 510 and 518 of Figure 5); and an evaluation module (e.g., pg. 34, lns. 16-18), after each question for: evaluating, answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score (e.g., pg. 34, lns. 16-20; 308 of Figure 310); varying a threshold as a function of said estimated score (e.g., pg. 34, lns. 18-28, Figure 3); and dynamically modify said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold (e.g., pg. 34, ln. 18 - pg. 35, ln. 2; pg. 47, lns. 18-19; Figure 3).

According to independent claim 35, a method of dynamically administering a test to assess one or more domains, comprises the steps of: generating a customized test, based on a respondent's characteristics and one or more domains selected by the respondent or test provider, said test having a plurality of questions for said respondent in accordance with said selected domains (pg. 14, ln. 28 – pg. 15, ln. 20; pg. 25, lns. 3- 8; pg. 34, lns. 5-20; 504-518 of Figure 5); administering said test by providing one question at a time to said respondent (e.g. pg. 25, ln. 8-17, pg. 34, lns. 15-16, 510 and 518 of Figure 5); and after each question: evaluating answers provided by said respondent to administered questions to estimate a score and a confidence level in the accuracy of said estimated score (e.g., pg. 34, lns. 16-20; 308 of Figure 310); varying threshold as a function of said estimated score (e.g., pg. 34, lns. 18-28, Figure 3); and dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold (e.g., pg. 34, ln. 18 - pg. 35, ln. 2; pg. 47, lns. 18-19; Figure 3).

According to claim 29, a computer readable media (pages 40-41) controls a computer to perform the steps of: generating a customized test, based on the patient's characteristics and one or more health domains selected by a patient or a health care provider, said test having a plurality of questions for said patient in accordance with said selected health domains (pg. 14, ln. 28 – pg. 15, ln. 20; pg. 25, lns. 3- 8; pg. 34, lns. 5-20; 504-518 of Figure 5); administering said test by providing one question at a time to said patient(e.g. pg. 25, ln. 8-17, pg. 34, lns. 15-16, 510 and 518 of Figure 5); and after each question: evaluating answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score (e.g., pg. 34, lns. 16-20; 308 of Figure 310); and varying a threshold as a

function of said estimated score (*e.g.*, pg. 34, lns. 18-28, Figure 3); dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold (*e.g.*, pg. 34, ln. 18 - pg. 35, ln. 2; pg. 47, lns. 18-19; Figure 3).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1-6, 8-23, 25-27, 29-41 are unpatentable under 35 U.S.C. §103(a) over Ware et al., *Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures*, THE QUALITY OF LIFE NEWSLETTER, JANUARY 1999-APRIL 1999 (“Ware”) in view of U.S. Patent No. 5,059,127 (“Lewis”)?

B. Whether claims 42-45 are unpatentable under 35 U.S.C. §103(a) over Ware in view of U.S. patent No. 6, 6067, 523 (“Bair”)?

VII. ARGUMENT

Claims 1-6, 8-23, 25-27, and 29-41 have been rejected under 35 U.S.C. § 103(a) over Ware in view of Lewis. Claims 42-45 have been rejected under 35 U.S.C. § 103(a) over Ware in view of Bair. A *prima facie* case of obviousness has not been shown because neither Ware, Lewis, or Bair individually or in combination teach or suggest *all* the limitations of claims 1-6, 8-23, 25-27, 29-41, and 42-45.

A. Combined References Do Not Teach Or Suggest All the Claim Limitations

To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must not be based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP § 2143. Here, a *prima facie* case of obviousness has not been shown because neither Ware, Lewis, or Bair individually or in combination teach or suggest *all* the limitations of claims 1-6, 8-23, 25-27, 29-41, and 42-45.

1. Rejection Under 35 U.S.C. § 103 Over Ware in View of Lewis (Claims 1-6, 8-23, 25-27, 29-41)

Claims 1-6, 8-23, 25-27, 29-41 each require "varying a threshold as a function of said estimated score." Neither Ware nor Lewis either taken alone or in combination teaches or suggests this limitation. Appellants respectfully submit that only the present invention teaches or suggests varying the threshold as a function of the estimated score, as required by claims 1-6, 8-23, 25-27, and 29-41.

Appellants submit that Ware describes a health assessment method that utilizes a fixed, unvarying, set or preset standards of precision within a single health assessment, whereas the

present invention provides a method of assessing the health status or health care of a patient wherein the threshold varies as a function of the estimated score within or during a single test. As such, the present invention provides a flexibility in the administration of a health related test by mimicking the evaluation process performed by a professional health care provider. The present invention provides such flexibility by varying the threshold as a function of the estimated score during the test. In particular, during the administration of the test, the threshold will be raised for a health condition aspect of particular interest and will be lowered for a health condition aspect of lesser interest. In so doing, the present invention streamlines the process by not requiring an unnecessary amount of additional questions for health conditions which are of reduced interest, while requiring an increased number of questions related to a health condition of particular interest. This advantage of the present invention raises the statistical accuracy and focus of the test, while at the same time reducing the burden on the test subject.

The Examiner asserts that “Ware teaches that the threshold (i.e. precision standard based on the confidence interval) varies as a function of the estimated score.” (Final Office Action, page 4). For support regarding the Examiner’s position, the Examiner cites to Ware at page 12 col. 1-2 and states:

Ware discloses the following steps in Figures 3: step 3) re-estimating the score, step 4) re-estimating the confidence interval, step 5) determining whether a stopping rule is satisfied and determining whether the score has been estimated within a preset standard of precision based on the confidence interval, wherein once the precision standard is met, the computer either begins assessing the next concept or ends the battery (considered to be a form of ‘threshold’), wherein the precision standard based on the confidence interval (i.e., the threshold) is set based on each patient’s score (see page 12, col. 1-2). . . . Note, Ware’s discussion of where the preset standard of precision is +/-5.4 for the lowest scoring patients, where these patients scored near or below an established cutoff point used in screening patients for psychiatric disorders. Note, Ware discloses that the standard of precision was relaxed to +/-7.9 or less for patients at or above the 90th percentile.

(Final Office Action, pages 3-4) (emphasis added).

Contrary to the Examiner's assertions on both pages 3-4 and page 10 of the Final Office Action, Ware does not show that the threshold varies during the administration of the test. "Re-estimating the score" and "re-estimating the confidence level" does not affect or change the constant "preset standard of precision" (i.e., threshold) to which the variable score and confidence level are compared. In fact, the prior Examiner who was responsible for the August 3, 2007 Office Action, even admitted therein that Ware is deficient because it does not teach "varying a threshold as a function of said estimated score; and dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold" (August 3, 2007 Office Action at 3). The passages cited by the current Examiner in the Final Office Action merely show that Ware sets different precision standards for different groups of patients (low vs. high scoring patients). In fact, these passages from Ware cited by the Examiner clearly support appellants position that Ware does not teach or suggest varying the threshold during the administration of a test. Varying the threshold, of course, is a unique feature recited by claims 1-6, 8-23, 25-27, and 29-41.

Moreover, appellants respectfully submit that one of ordinary skill in the art would not find that modifying the different preset precision standards in Ware, which are fixed for different groups of patients (low vs. high scoring patients), is equivalent to varying the threshold during the administration of a single test as a function of the estimated score as required by claims 1-6, 8-23, 25-27, and 29-41. Therefore, the Examiner has failed to show that Ware teaches or suggests varying the threshold as a function of the estimated score during that administration of a test.

Lewis also does not teach or suggest "varying a threshold *as a function of said estimated score*" as required by all the claims of the present invention (emphasis added). While Lewis teaches "assigning variable threshold variables to particular testlets," as cited by the Examiner, (Final Office Action at 4), Lewis does not teach or suggest varying a threshold "*as a function of said estimated score*" as required by the claims. Lewis teaches assigning variable threshold variables generally in the context of preparing a *random* testlet selection (*see, e.g.*, Lewis, col. 9, lns. 6-9). This is diametrically opposed to "varying a threshold *as a function of said estimated score*" which is based on and results in a dynamic method akin to an adaptive testing method. In

the Final Office Action at 10, the Examiner insists that Lewis “teaches the concept of carrying a threshold as a function of a score with testlets” (Final Office Action at 10) and cites col. 9 lns 5-10 of Lewis: “random testlet selection requires . . . a method of assigning variable threshold variables to particular testlets.” (Lewis, col. 9, lns. 5-10). The cited passage, however, does not translate into “varying a threshold as a function of said estimated score” as alleged by the Examiner. The Examiner’s misreading ignores a critical difference between Lewis and the present invention. Namely, Lewis randomly or variably selects a *constant* threshold per testlet; whereas the present invention is a much more versatile adaptive test that *varies* a threshold during the test as a function of an estimated score. Contrary to the Examiner’s assertion, Lewis simply does not teach varying *the threshold* during the administration of the test.

Lewis actually teaches away from an *adaptive* testing method by disparaging such a method as complicated and not easily implemented. (see e.g., Lewis, col. 8 ln. 61 – col. 9, ln. 13). For example, Lewis states that “the primary reasons for selecting *random* rather than *adaptive* [include] (i) computational efficiency: . . . (ii) simplicity . . . ; [and] (iii) ease of implementation”; Lewis also states that “the additional complication of an adaptive testlet selection mechanism is . . . *not particularly desirable.*” (see e.g., Lewis, col. 8 ln. 61 – col. 9, ln. 13). As such Lewis actually teaches away from the testing method of the claims of the present invention which require varying a threshold “as a function of said estimated testscore.” The prior art must to be judged based on a full and fair consideration of what that art teaches, not by using Applicants invention as a blueprint for gathering various bits and modifying the pieces in an attempt to reconstruct Applicant’s invention. The Examiner cannot simply change the principle of the operation of the reference or render the reference inoperable for its intended purpose to render the claims unpatentable.

Moreover, assuming *arguendo* that Lewis and the present invention similarly are directed to providing a testing system with the motivation to “balance the goals of classification accuracy and test efficiency” as stated by the Examiner (Final Office Action at 12 at 3), Lewis’ solution for achieving such a result is entirely opposite to that taught by the present invention. Lewis is directed to “mastery testing” which is “used in educational and certification contexts to decide, on the basis of test performance, whether or not an individual has attained a specified level of

knowledge, or mastery, of a given subject.” (Lewis, ABSTRACT, col. 1, lns. 19-23). As such, in order to achieve the goal of balancing the classification accuracy and test efficiency, Lewis describes randomly selecting a testlet (*see, e.g.*, Lewis, col. 8, lns. 61-62) wherein the method may randomly assign threshold variables to the testlets. (*see, e.g.*, Lewis, col. 9, lns. 6-9). The present invention, on the other hand, is specifically directed to *dynamically* changing the content of the selected testlet based on the response (answers) to the questions by the test taker, while the test is occurring. As such, the present invention provides flexibility in the administration of a health related test by mimicking the evaluation process performed by a professional health care provider. Even if the testlet is wrongly selected, the present invention allows for the system to adapt during the administration of the testlet, whereas none of the cited art is even remotely concerned with such a problem. At best, even if the references were combined as suggested by the Examiner, the combination would merely teach how to select the right test prior to the actual administration of the selected testlet. The present invention, on the other hand, addresses the problem of dynamically altering a test concurrently being given in the event that it is determined that the testlet being given is wrong. Specifically, the claims of the present invention provide an adaptive testing method which include the novel steps of “varying a threshold *as a function of said estimated score*” and “dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold.” As such Lewis teaches away from the testing method provided by the present invention.

Moreover, while the Examiner cites *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) and quotes “*In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006)” (Final Office Action at 12) to point out that rejections on obviousness “need not seek out precise teachings directed to the specific subject matter,” applicants also stress the United States Supreme Court *warning* in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) that

A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. *See Graham*, 383 U. S., at 36 (warning against a ‘temptation to read into the prior art the teachings of the invention in issue’ and instructing courts to ‘guard against slipping into the use of hindsight’ . . .)

“To imbue one of ordinary skill in the art with knowledge of the present invention, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim of the insidious effect of hindsight syndrome, wherein that which only the inventor taught is used against the teacher.” *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983).

Nowhere do Ware or Lewis solely or in combination teach “varying a threshold *as a function of said estimated score*” as required by claims 1-6, 8-23, 25-27, and 29-41. Therefore, the Examiner has failed to establish a *prima facie* case of obviousness for claims 1-6, 8-23, 25-27, and 29-41.

2. Rejection Under 35 U.S.C. § 103 Over Ware in View of Bair (Claims 42-45)

Furthermore, the Examiner rejects dependent claims 42-45 as being unpatentable over Ware in view of Bair. (Final Office Action at 9). Bair, however, fails to teach or suggest “varying a threshold *as a function of said estimated score*” and “dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold” as required by claims 42-45 as dependent from claim (Final Office Action at page 9). Bair merely describes generating a test from a master question table and skipping certain related questions based on the answer to the first related question. *See* col. 11, line 45 - col. 13, line 12. For example, if the patient answers that she has no history of drug abuse, then the drug related questions (i.e., what drugs are you taking) will be skipped. There is no disclosure in Bair related to use of a threshold as a function of the estimated score during the administration of a test. Nowhere do Ware (as explained above in section A) and Bair, solely or in combination teach “varying a threshold *as a function of said estimated score*” and “dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold” as required by all the claims of the present invention. Therefore, the addition of Bair does not cure the afore-explained deficiency of Ware, and the combination of Ware and Bair does not teach or suggest varying the threshold as a function of the estimated score as required by claims 42-45. Therefore, the Examiner has failed to establish a *prima facie* case of obviousness for claims 42-45.

B. There Is No Motivation To Combine References
(Claims 1-6, 8-23, 25-27, 29-41, 42-45)

The Examiner has also failed to establish a *prima facie* case of obviousness because there is no motivation to combine these references. With respect to the combination of Ware and Lewis, as explained above, Lewis is directed to a mastery system that teaches away from an adaptive test method wherein the threshold value is based on a specific element. Moreover, neither Ware, Lewis, nor Bair suggest the desirability of the claimed invention because either Ware, Lewis nor Bair is even remotely concerned with the problem of providing flexibility in the administration of a health test by mimicking the evaluation process performed by a professional health care provider. Typically, the health care provider administering the test may inquire more deeply into certain issues (related to specific domains) raised by the patient's answer if the patient scored poorly, whereas additional questions related to domains which are of reduced interest would not be asked. For example, if a person has difficulty walking up the stairs due to leg pain without shortness of breath or chest pain, a health care provider will want to gather more information regarding the leg pain. This could be done by more focused questions directed to the history of the leg pain, e.g., how long have you had the pain, how severe is the pain on a scale of 1-10, when does it hurt the most, and by ordering further tests like an x-ray or MRI. The health care provider will not inquire further regarding possible issues related to shortness of breath or chest pain, because it was found out that this is not the reason that the patient is having difficulty walking up the stairs.

The present invention provides such flexibility by varying the threshold as a function of the estimated score during the test. In particular, during the administration of the test, the threshold will be raised for a domain of particular interest and will be lowered for a domain of lesser interest. In so doing, the present invention streamlines the process by not requiring an unnecessary amount of additional questions for domains which are of reduced interest, while requiring an increased number of questions related to a domain of particular interest. This advantage of the present invention raises the statistical accuracy and focus of the test, while at the same time reducing the burden on the test subject. It is undeniable that neither Ware nor Bair individually or in combination therewith are even remotely concerned with providing such

flexibility. Since Appellants have recognized a problem not addressed by the cited prior art and solved that problem in a manner not suggested by cited prior art, the basis for patentability of the claims is established. See *In re Wright*, 6 U.S.P.Q. 2d, 1959, 1961-1962 (Fed. Cir. 1988). There, the CAFC relied upon previous decisions requiring a consideration of the problem facing the inventor in reversing the Examiner's rejection. "The problem solved by the invention is always relevant". *Id.* at 1962. See also, *In re Rinehart*, 189 U.S.P.Q. 143, 149 (CCPA 1967), which stated that the particular problem facing the inventor must be considered in determining obviousness.

Therefore, Ware, Lewis, or Bair independently or in combination do not teach or suggest "varying a threshold *as a function of said estimated score*" and "dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold" as required by all the pending claims. Therefore, the Examiner has failed to establish a *prima facie* case of obviousness for claims 1-6, 8-10, 12-15, 17-23, 25-27, and 29-45.

VIII. CONCLUSION

In view of the foregoing, Appellants respectfully submit, that all pending claims 1-6, 8-10, 12-15, 17-23, 25-27, and 29-45 are nonobvious under 35 U.S.C. §103 because the Examiner failed to establish a *prima facie* case of obviousness. Therefore, appellants request that the Board reverse the pending grounds for rejection.

Dated: July 14, 2008

Respectfully submitted,



By
C. Andrew Im

Registration No.: 40,657
FULBRIGHT & JAWORSKI L.L.P.
666 Fifth Avenue
New York, New York 10103
(212) 318-3000
(212) 318-3400 (Fax)
Attorney for Applicant

CLAIMS APPENDIX
(37 C.F.R. § 41.37(C)(VIII))

LISTING OF CLAIMS ON APPEAL

Claims Involved in the Appeal of Application Serial No. 09/873,500

1. A method of assessing the health status or health care of a patient, comprising the steps of:
 - generating a customized test, based on the patient's characteristics and one or more health domains selected by a patient or a health care provider, said test having a plurality of questions for said patient in accordance with said selected health domains;
 - administering said test by providing one question at a time to said patient; and
 - after each question:
 - evaluating answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score;
 - varying a threshold as a function of said estimated score; and
 - dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold.
2. The method of claim 1, further comprising the step of generating a report regarding the health status of said patient.
3. The method of claim 1, wherein said domain is a condition experienced or perceived by said patient.
4. The method of claim 1, wherein the step of dynamically modifying includes the step of ranking said plurality of questions in accordance with said estimated score; and selecting a question from said plurality of questions based on said ranking that has not been administered to said patient.

5. The method of claim 4, wherein the step of selecting comprises selecting a highest rank question.
6. The method of claim 1, wherein the step of dynamically modifying includes the step of terminating said administration of said test if it is determined that said estimated confidence level is within said threshold.
8. The method of claim 1, wherein the step of generating selects said questions for said domain from a database having questions and answers pertaining to a plurality of domains.
9. The method of claim 1, wherein the step of administering includes the step of providing a list of possible answers for each question to said patient.
10. The method of claim 1, wherein the step of estimating includes the step of statistically analyzing said answers provided by said patient for errors or consistency.
12. The method of claim 1, wherein the step of estimating includes the step of statistically analyzing said answers provided by said patient for estimating non-responsive answers to said test.
13. The method of claim 2, wherein the step of reporting includes the step of comparing said answers provided by said patient with answers provided by other patients in said domain.
14. The method of claim 1, wherein the step of administering includes the step of administering said test to said patients over a network, wherein said network is one of the following: an Internet, an intranet, a telephone network, and a wireless network.

15. The method of claim 2, wherein the step of generating reports includes the step of generating said report over a network.
17. The method of claim 1, wherein said domain includes at least one of the following: severity of headaches, level of depression, degree of personal mobility, self-perceived status, effectiveness of a treatment, physical health, emotional health, impact of asthma, job satisfaction, opinion polling, personality test, customer satisfaction and general overall health.
18. A computer based system for assessing the health status or health care of a patient, comprising:
 - a test module for generating a customized test, based on the patient's characteristics and one or more health domains selected by a patient or a health care provider, said test having a plurality of questions for said patient in accordance with said selected health domains;
 - an administration module for administering said test by providing one question at a time to said patient; and
 - an evaluation module, after each question for:
 - evaluating, answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score;
 - varying a threshold as a function of said estimated score; and
 - dynamically modify said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold.
19. The system of claim 18, further comprising a report module for generating a report regarding the health status of said patient.
20. The system of claim 18, wherein said domain is a condition experienced or perceived by said patient.

21. The system of claim 18, wherein said evaluation module is operable to rank said plurality of questions in accordance with said estimated score and select a question from said plurality of questions based on said ranking that has not been administered to said patient.
22. The system of claim 21, wherein said evaluation module is operable to select a highest rank question.
23. The system of claim 18, wherein said administration module is operable to terminate said administration of said test if it is determined that said estimated confidence level is within said threshold.
25. The system of claim 18, wherein said test module is operable to generate said questions for said domain from a database having questions and answers pertaining to a plurality of domains.
26. The system of claim 18, wherein said administration module is operable to provide a list of possible answers for each question to said patient.
27. The system of claim 18, wherein said evaluation module is operable to statistically analyze said answers provided by said patient for errors or consistency.
29. The system of claim 18, wherein said evaluation module is operable to statistically analyze said answers provided by said patient for estimating non-responsive answers to said test.
30. The system of claim 19, wherein said reporting module is operable to compare said answers provided by said patient with answers provided by other patients in said domain.

31. The system of claim 18, wherein said administration module is operable to administer said test to said patients over a network.
32. The system of claim 19, wherein said reporting module is operable to generate said report over a network.
33. The system of claim 31, wherein said network is one of the following: an Internet, an intranet, a telephone network, and a wireless network.
34. The system of claim 18, wherein said domain includes at least one of the following: severity of headaches, level of depression, degree of personal mobility, self-perceived status, effectiveness of a treatment, physical health, emotional health, impact of asthma and general overall health.
35. A method of dynamically administering a test to assess one or more domains, comprising the steps of:
 - generating a customized test, based on a respondent's characteristics and one or more domains selected by the respondent or test provider, said test having a plurality of questions for said respondent in accordance with said selected domains;
 - administering said test by providing one question at a time to said respondent; and after each question:
 - evaluating answers provided by said respondent to administered questions to estimate a score and a confidence level in the accuracy of said estimated score;
 - varying threshold as a function of said estimated score; and
 - dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold.
36. The method of claim 35, wherein the step of dynamically modifying includes the step of terminating said administration of said test if it is determined that said estimated confidence level is within said threshold.

37. The method of claim 35, wherein said domain is one or more health related or non-related conditions.
38. The method of claim 37, wherein said domain includes at least one of the following: severity of headaches, level of depression, degree of personal mobility, self-perceived status, general overall health, effectiveness of a treatment, job satisfaction, opinion polling, personality test, and customer satisfaction.
39. A computer readable media for controlling a computer to perform the steps of: generating a customized test, based on the patient's characteristics and one or more health domains selected by a patient or a health care provider, said test having a plurality of questions for said patient in accordance with said selected health domains; administering said test by providing one question at a time to said patient; and after each question: evaluating answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score; and varying a threshold as a function of said estimated score; dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold.
40. The computer readable media of claim 39, wherein the step of dynamically modifying includes the step of terminating said administration of said test if it is determined that said estimated confidence level is within said threshold.
41. The method of claim 1, wherein at least two domains are selected to be assessed.
42. The method of claim 1, wherein said step of administering said test further comprises the step of administering said test before a variable is introduced, wherein said variable includes one of the following: a pharmaceutical, drug composition change, therapeutic method, health care provider, health care regimen, environmental change, lifestyle change, or work change, and further comprising the steps of: readministering said test after said variable is introduced; and

comparing resultant data obtained from each separate administration of said test, wherein said resultant data is indicative of efficacy or impact of the introduction of said variable on said health status or health care of said patient.

43. The computer based system of claim 18, wherein said administration module is operable to:

administer said test before a variable is introduced, wherein said variable includes one of the following: a pharmaceutical, drug composition change, therapeutic method, health care provider, health care regimen, environmental change, lifestyle change, or work change;

readminister said test after said variable is introduced; and

wherein said system further comprises a comparison module for comparing resultant data obtained from each separate administration of said test by said administration module, wherein said resultant data is indicative of efficacy or impact of the introduction of said variable on said health status or health care of said patient.

44. The method of claim 35, wherein said step of administering said test further comprises the step of administering said test before a variable is introduced, wherein said variable includes one of the following: a pharmaceutical, drug composition change, therapeutic method, health care provider, health care regimen, environmental change, lifestyle change, or work change, and further comprising the steps of:

readministering said test after said variable is introduced; and

comparing resultant data obtained from each separate administration of said test, wherein said resultant data is indicative of efficacy or impact of the introduction of said variable on said health status or health care of said respondent.

45. The computer readable media of claim 39, wherein said step of administering said test further comprises the step of administering said test before a variable is introduced, wherein said variable includes one of the following: a pharmaceutical, drug composition change, therapeutic method, health care provider, health care regimen, environmental change, lifestyle change, or work change, and further comprising the steps of:

readministering said test after said variable is introduced; and
comparing resultant data obtained from each separate administration of said test,
wherein said resultant data is indicative of efficacy or impact of the introduction of said
variable on said health status or health care of said patient.

EVIDENCE APPENDIX
(37 C.F.R. § 41.37(C)(IX))

None.

RELATED PROCEEDINGS
APPENDIX
(37 C.F.R. § 41.37 (C)(X))

There have been no decisions rendered by a court or the Board in any proceeding identified above in section II.